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28075 7590 06/10/2010 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JILL McFADDEN, EARL BARDSLEY, and ROBERT GARABEDIAN

Appeal 2009-013608 Application 09/097,023 Technology Center 3700

Decided: June 10, 2010

Before TONI R. SCHEINER, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 by the Patent Applicant from the Patent Examiner's rejections of claims 51 and 52 in U.S. Application 09/097,023. The Board's jurisdiction for this appeal is under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The claimed invention is directed to a catheter. Claims 51 and 52 are pending and stand rejected by the Examiner under 35 U.S.C. § 103(a) as obvious in view of Samson (U.S. Pat. 5,702,373, issued Dec. 30, 1997) and Andersen (U.S. Pat. 5,662,713, issued Sep. 2, 1997). Claim 51 is illustrative and reads as follows:

51. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:

a relatively stiff proximal segment including an inner proximal liner, an outer proximal cover, and a braid interposed between the inner proximal liner and the outer proximal cover; and

a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a single strand, wherein the single strand forms a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand;

wherein the knit tubular member is generally not radially expandable.

STATEMENT OF THE ISSUES

The issues in this rejection are:

- 1) Whether a "generally not radially expandable" knit member, as recited in claim 51, was properly interpreted to encompass the self-expandable knit stent described in Andersen?
- 2) whether persons of ordinary skill in the art would have been prompted to replace the braid described in Samson's catheter with the knit stent member of Andersen?

PRINCIPLES OF LAW

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In making an obviousness determination, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

During patent examination, claim terms are given "the broadest reasonable meaning . . . in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

FINDINGS OF FACT ("FF")

- 1. Samson teaches that catheters can be used to deliver therapeutic and diagnostic agents to remote regions of the human body, and for treatment of diseases via angioplasty (Samson, at col. 1, 1, 25 to col. 2, 1, 7).
- 2. Samson describes a catheter comprising a braided metallic reinforcing member "situated . . . in such a way to create a catheter having an exceptionally thin wall, controlled stiffness, high resistance to kinking . . ." (Samson, Abstract).
- 3. Samson expressly defines a "braid" as a "tubular construction[] in which the ribbons making up the construction are woven in an in-and-out fashion

as they cross to form a tubular member defining a single lumen. The braids may be made up of a suitable number of ribbons" (*id.* at col. 12, ll. 14-20).

- 4. Andersen describes a stent for providing reinforcement to the lumen of a peristaltic organ (Andersen, at col. 1, ll. 50-53).
- 5. "The stent is knitted of metal wire to be self-expandable such that the stent expands outward against the body lumen wall by an elastic restoring force of the wire." (*Id.* at col. 1, ll. 64-67.)

ANALYSIS

Claims 51 and 52 are each directed to a catheter comprising a "knit tubular member" which "is generally not radially expandable." The knit tubular member "is formed from a single strand." The Examiner rejected the claims based on Samson's description of a catheter with a braid woven from a plurality of ribbons. The Examiner acknowledged that Samson did not describe a knit tubular member as recited in the claims, but determined that Andersen's knitted stent met the claimed element. The Examiner concluded that it would have been obvious to persons of ordinary skill in the art to have replaced the tubular braid in Samson's catheter with Andersen's knitted stent because "both perform the same function: adding rigidity to a tubular structure" (Ans. 5).

Appellants contend that the Examiner erred in determining that the claimed subject matter would have been obvious to persons of ordinary skill in the art. They argue that Andersen's knit stent does not meet the claimed limitation of a knit member which is "generally not radially expandable." (App. Br. 8-9.) Rather, Appellants argue that Andersen "need[s] the stent to be capable of expansion and contraction in order for the device to function

as intended." (*Id.* at 9.) Appellants also contend that there is no rationale for combining the disclosures of Samson and Andersen because "the established function of the expandable knitted stent of Anderson is quite different from the braid of the catheter of Samson." (Reply Br. 5.)

Appellants' position is supported by the evidence. As argued by Appellants, Andersen's stent is self-expandable (FF5) in contrast to the claimed tubular member which is explicitly recited in the claims to be "generally not radially expandable." (Claims 51 and 52.) The Examiner appeared to acknowledge this difference, but found that Andersen's stent "would be constrained by the liner when used in the invention of Samson so it would not expand radially." (Ans. 4.) In other words, the Examiner interpreted "generally not radially expandable" to be a property of the catheter assembly, not the tubular member itself.

The Examiner erred in interpreting the claim. Claims must be interpreted in light of the Specification. The Specification states that the "knit member . . . is not significantly radially expandable (e.g., does not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit member)." (Spec. 8: 17-20.) Based on this disclosure, persons of ordinary skill in the art would have recognized that the "generally not radially expandable" limitation is a property of the claimed single strand knit member, not the entire catheter assembly with a liner as found by the Examiner. As Andersen's knit stent is expandable (FF5), Andersen does not describe the "generally not radially expandable" knit member of the claimed invention.

Additionally, there would have been no reason to combine Samson and Andersen. As argued by Appellants, Samson describes a stiff catheter

(FF2), while Andersen's is self-expandable – a property necessary for it to provide lumen reinforcement (FF4-5). The Examiner's determination that the Samson and Anderson structures "perform the same function" by "adding rigidity" (Ans. 5) is therefore not supported by the evidence, undermining the Examiner's reasoning.

CONCLUSIONS OF LAW & SUMMARY

The phrase "generally not radially expandable" was not properly interpreted to encompass the self-expandable knit stent described in Andersen. There is insufficient evidence to establish that persons of ordinary skill in the art would have been prompted to replace the braid described in Samson's catheter with the knit stent member of Andersen. The obviousness rejections of claims 51 and 52 are reversed.

REVERSED

cdc

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